

Written Questions
from the Special 301 Subcommittee of the Trade Policy Staff Committee
in Docket No. USTR-2020-0041
Washington, D.C.
February 22, 2021

Instructions

Due to COVID-19, USTR is fostering public participation via written submissions rather than an in-person hearing. The Special 301 Subcommittee of the Trade Policy Staff Committee (Subcommittee) has reviewed written comments and poses the following clarifying questions to commenters.

1. The question or questions posed to you by the Subcommittee are directly after the name of your government, organization, or company in this document. If the name of your government, organization, or company is not located below, that means the Subcommittee did not pose any questions for you.
2. Place your responses in a separate Microsoft Word (.doc) or Adobe Acrobat (.pdf) document and name the document “Response to Questions [Commenter Name, Organization, or Government].”
3. On or before March 5, 2021 at 11:59 p.m. EST, submit the document electronically via *Regulations.gov* using docket number USTR-2020-0041.

The Federal Register Notice at <https://www.federalregister.gov/documents/2020/12/15/2020-27515/request-for-comments-and-notice-of-a-public-hearing-regarding-the-2021-special-301-review> contains further information. Email Special301@ustr.eop.gov if you need clarification on the written questions, submission procedures, or deadlines.

Table of Contents

Government of Bulgaria	3
Government of Colombia	4
Government of Costa Rica.....	5
Government of the Czech Republic.....	6
Government of Ecuador	7
Government of Greece	8
Government of Indonesia.....	9
Government of Malaysia.....	10
Government of Pakistan.....	11
Government of Philippines	12
Government of the Republic of Korea.....	13
Government of Saudi Arabia	14
Government of Taiwan	15
Government of Thailand	16
Government of the United Arab Emirates	17
Government of Ukraine	18
ACT The App Association.....	19
Alliance for Safe Online Pharmacies	20
Alliance for Trade Enforcement	21
American Chamber of Commerce in Argentina	22

American Apparel & Footwear Association	23
American University Washington College of Law, Program on Information Justice and Intellectual Property	24
Asia Video Industry Association	25
Association for Accessible Medicines	26
Audiovisual Anti-Piracy Alliance	27
beIN Media Group, LLC and Miramax, LLC	28
Biotechnology Innovation Organization	29
Brazil National Confederation of Industry and American Chamber of Commerce for Brazil	30
BSA The Software Alliance	31
China Chamber of International Commerce	32
CIOFORA	33
The Clear Sky Initiative	34
Computer & Communications Industry Association	35
Confederation of Indian Industry	36
Consortium for Common Food Names	37
Emirates Intellectual Property Association	38
Engine Advocacy	39
The Football Association Premier League Limited	40
Footwear Distributors & Retailers of America	41
Fraunhofer USA	42
Indian Pharmaceutical Alliance	43
Intellectual Property Owners Association	44
International AntiCounterfeiting Coalition	45
International Intellectual Property Alliance	46
International Olympic Committee	47
Internet Association	48
Knowledge Ecology International	49
La Liga Nacional de Fútbol Profesional	50
MFJ International, LLC	51
National Association of Manufacturers	52
National Milk Producers Federation and U.S. Dairy Export Council	53
Pharmaceutical Research and Manufacturers of America	54
Public Citizen	55
The Sports Coalition	56
Trademark Working Group	57
Union of European Football Associations	58
U.S. Chamber of Commerce	59
U.S.-India Strategic Partnership Forum	60

Government of Bulgaria

1. Your submission notes that current law does not allow prosecutors to engage in the practice of evidence sampling in the investigation of intellectual property crimes. Does the Bulgarian government have any plans to introduce legislation that would allow evidence sampling in intellectual property cases?

Government of Colombia

1. Regarding internet service provider (ISP) liability, your submission notes that Colombian technical institutions met four times in 2020 to prepare a draft text of the law, however meetings were suspended.
 - a. Are there plans to restart the meetings?
 - b. What is the status of the draft text of the law?
2. Please provide more detail on the timeline for developing a proposal to set prices of new drugs based on therapeutic value. Is stakeholder feedback being taken into account when developing the proposal?

Government of Costa Rica

1. On government use of licensed software, your submission states that the IP Registry “has already processed all data submitted in 2020 and will issue the required report.”
 - a. Can you provide a timeline of when the IP Registry’s report will be issued and explain what the next steps are after the Ministry of Justice submits the report to the Costa Rican president?
 - b. According to the data gathered, what percentage of agencies comply with the requirements of Executive Decree N°37549-JP to only use licensed software?
 - c. When are agencies required to submit 2021 data to the IP Registry?
2. On border enforcement, your submission states that the issuance and implementation of “DIR-DN 0004-2019: General Guidelines under the Law on Procedures for Enforcement of Intellectual Property Rights” is “a step in the right direction and allows for all customs authorities to share a unified database.” Can you explain any near-term steps planned to implement the General Guidelines?
3. Your submission identifies Executive Decree 36880-COMEX-JP, amended by Executive Decree 41557-COMEX-JP, which “allows for ISPs to execute the notice and takedown procedures according to their internal capabilities, provided they are carried out in an expeditious, prudential, timely, and reasonable manner.”
 - a. Can you elaborate on the impact of this Executive Decree to online piracy in Costa Rica in the past year?
 - b. Have there been any court cases or judicial decisions on the procedures?

Government of the Czech Republic

1. In your submission, you noted that “methods for committing IPR related crimes are becoming more sophisticated with the advancement and greater availability of new technologies and with international dimension of the problem.” Would you please tell us a little more about how you are adjusting enforcement efforts to address this advancement in technology? How are you detecting online piracy and counterfeiting?

Government of Ecuador

1. Your submission notes that in 2020, SENADI worked on a proposal to reform the penal code to add camcording and other activities as criminal activities.
 - a. In addition to camcording, what other activities are proposed as criminal activities? What is the status of the proposal?
 - b. Your submission responds to right holder complaints about unauthorized camcording by stating that it would be “helpful to receive information regarding those right holders who have initiated any actions in Ecuador to see their rights enforced.” Please describe the interactions you have had with right holders over the past year regarding unauthorized camcording, and what additional information or interactions with right holders would be helpful to the Government of Ecuador.

Government of Greece

1. Several ministries within your government filed submissions. Would you please describe how these different ministries and any other ministry tasked with responsibility for intellectual property cooperate on intellectual property protection and enforcement?
2. The submission of the Ministry of Development and Investments notes that in July 2020 the creation of the Interagency for Market Control (DI.M.E.A.) took place. As this organization unifies Hellenic Enforcement Authorities (Police, Port Police, Customs, etc.) to enhance cooperation and share intelligence, can you clarify whether this cooperation will focus on the illicit trade in both physical and online goods? If not, then could you clarify why not?
3. Your submission from the Ministry of Development and Investments noted an update to the law providing greater penalties for trade in counterfeit and pirated goods, including seizure. Do enforcement agencies have the authority to destroy goods that are seized? If not, what happens to seized goods?
4. The Hellenic Copyright Organization submission mentions an amendment to Article 66E of the Greek Copyright Law, specifically paragraph 10A. According to the submission, this paragraph provides for a special procedure allowing for immediate preventive measures in respect of national/international television events, primarily related to the live transmission of cultural or sport events. Could you provide clarifying information as to the exact nature of this procedure, such as does the procedure allow for immediate measures against illicit or unauthorized live transmissions and, if so, what form do these measures take?

Government of Indonesia

1. Your submission notes several items in Law No. 11 of 2020 on Job Creation that are relevant for trade and investment, including amendments to the Patent Law. However, U.S. companies continue to raise concerns with Indonesia's Patent Law, including narrow patentability criteria, disclosure requirements with respect to traditional knowledge and genetic resources, and licensing recordal requirements. Can you explain Indonesia's plans to address these concerns?
2. Your submission states that Law No. 11 of 2020 on Job Creation "provided amendments to the Patent Law, to include introducing new criteria to, amongst others, protect, shorten and simplify patent procedures." Can you further explain the "new criteria to . . . protect, shorten and simplify patent procedures"?
3. Your submission notes that in 2020, there were 35 copyright cases brought before the Directorate of Investigation and Dispute Settlement of the Directorate General of Intellectual Property based on complaints by right holders.
 - a. What was the cause of the increase in the number of copyright cases between 2019 and 2020? Did more right holders submit complaints, or did a similar number of individual right holders submit greater numbers of complaints?
 - b. What was the outcome of the 35 copyright cases noted in 2020?
4. In your written submission, Indonesia stated that, as of January 2021, there are six companies that have "registered their IP products with Directorate General of Customs and Excise" in light of Government Regulation No. 20 of 2017. Can you describe whether all industry stakeholders are able to record their IP at the Customs office, how many enforcement actions Customs officials have taken since the regulation was implemented, and whether right holder complaints are needed before Customs officials take enforcement action at the border?
5. On intra-government cooperation on IP enforcement, your submission states that Indonesia "is currently planning to reactivate National IP Task Force" and that the "[t]he first step is to revise the presidential decree as an umbrella for the formation of" the task force. Can you explain when the relevant presidential decree will be revised and when the National IP Task Force will be reactivated?
6. Your submission states that Indonesia is "currently in the process of drafting a Presidential Regulation on the Investment Priority List which will abolish investment restriction, except through foreign equity limitation." Can you provide further information on this draft Presidential Regulation and whether it is intended to replace the Presidential Regulation No. 44 of 2016 on the Negative Investment List? Would this Presidential Regulation address longstanding concerns stemming from the 2009 Film Law, including local screen quotas and prohibitions on dubbing of imported films? If not, can you explain Indonesia's plans to address these concerns?

Government of Malaysia

1. Your submission states that Malaysia held public consultations on potential amendments to the Patents Act 1983. Procedurally, what is the status of amending the Patents Act 1983, and what are the next steps and timing of those steps?
2. Your submission states that Malaysia is “in the midst of reviewing the Copyright Act” and that the proposed amendments “will strengthen the enforcement of copyright among others in terms of providing the provision to take criminal action against online piracy.”
 - a. When does Malaysia plan to release a draft of the new copyright law for public review and comment?
 - b. How will Malaysia engage with copyright stakeholders and foreign governments during this review process?
3. The 2021 Special 301 submission by the International AntiCounterfeiting Coalition states that right holders were “frustrated by tip-offs to offenders, as well as instances where officers unnecessarily and inexplicably delayed carrying out raids, allowing counterfeiters time to remove illicit goods from the targeted premises.” Can you explain steps Malaysia has taken or can take to address these concerns?
4. USTR has identified the Petaling Street Market in Kuala Lumpur as a notorious market for selling large volumes of counterfeit goods for several years, yet right holders continue to report difficulties in initiating enforcement activities, including due to the involvement of organized crime at this market. How does Malaysia intend to address this issue?

Government of Pakistan

1. Your submission states that there are proposed amendments to Pakistan’s intellectual property laws, including the Patent Ordinance, the Copyright Ordinance, and the Trademark Ordinance.
 - a. What is the projected timeline for these proposed amendments to be enacted?
 - b. According to your submission, the amendments introduce minimum penalties and enhanced punishments for trademark infringement to deter counterfeiting. What are the minimum penalties and enhanced punishments referred to in your submission?
2. Your submission states that the “Federal Government has taken up establishment of two more” intellectual property Tribunals. Please elaborate on the timeframe for establishing those Tribunals.
3. Your submission identifies January 2020 as the deadline for integrating “Customs IPR Directorates all over the country” “within the WEBOC Electronic Customs Clearance system.” Was that deadline met? If not, what were the reasons for the delay, and when will the Directorates be integrated?
4. Your submission notes that a total of 3890 copyright registration applications were received and 2306 were granted registration.
 - a. What were the reasons for not granting registration to the 1584 remaining applications?
 - b. What was the subject matter of the works granted registration?

Government of Philippines

1. The 2021 Special 301 submission by the American Apparel and Footwear Association states that “[n]o matter how effective the National Bureau of Investigation (NBI) and Intellectual Property Office of the Philippines (IPO-PHL) are, any raids that brands have successfully conducted end up in a broken criminal court system, resulting in years of legal bills, no accountability, and no deterring measures for counterfeiters.” Can you explain steps the Philippines has taken or can take to address these concerns?
2. The 2021 Special 301 submission by the International AntiCounterfeiting Coalition (IACC) states that right holders “had largely abandoned enforcement in the country” and “no matter the effort and resources applied by the NBI or IPO-PHL to clean up the local market . . . the case is going to move [to] the Philippines’ broken court system.” IACC’s submission also notes that some intellectual property cases in the courts have been pending for more than a decade. Can you explain steps the Philippines has taken or can take to address these concerns, including the pendency of intellectual property cases in its courts?

Government of the Republic of Korea

1. In response to industry concerns that your pharmaceutical pricing policies are inconsistent with Korea's commitments under KORUS, your submission notes that Korea conducts cost-effectiveness analyses on pharmaceuticals "with reference to GDP per capita." Do you use the most recent GDP per capital figures? If not, why not?
2. In the context of proposed amendments to the Copyright Act, your submission states that "there is no impact on the scope of rights granted by the Copyright Act to the rightsholders" with the introduction of the proposed simultaneous digital transmission right.
 - a. What are the substantive differences between the current right of interactive transmission, the current right of broadcasting, and the proposed simultaneous digital transmission right under Korea's related rights regime?
 - b. What type of transmission is the new proposed "simultaneous digital transmission" right intended to capture?
 - c. Please explain how transmissions under the proposed "simultaneous digital transmission right," if they are initiated at the request of the public, differ from the interactive uses under the making available right.
3. In the context of proposed amendments to the Copyright Act that would introduce a portrait right, your submission states that the current legislation already "requires obtaining permission of the person when producing films about the person (moral rights under civil law), thus the introduction of publicity rights does not create an unprecedented burden." Please provide the specific legal provision to which your submission refers.
4. Please elaborate on the accuracy of the statement in the 2021 Special 301 submission by the Alliance for Trade Enforcement that South Korea applies an "all-or-nothing" approach to patent term extensions by revoking an extension if an applicant appeals the length of a granted extension and then loses the appeal.
5. You state that a couple of international conventions support the use of screen quotas. Please identify these conventions and explain what grounds they provide.

Government of Saudi Arabia

1. Your submission states that SFDA believes that it does not violate the Regulations for the Protection of Confidential Commercial Information because “information [provided with the generic product] was acquired independently without relying on any information provided in the innovative product’s file.” Does SFDA interpret the Regulations consistent with Saudi Arabia’s statement in the Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization (WT/ACC/SAU/61 ¶ 261)? For example, for products covered by the 5-year term of protection provided to initial applicants under Article 5 of the Regulations, does SFDA require that the “information” submitted by the subsequent application for marketing authorization meet the same requirements applied to the initial applicant?
2. Your submission enumerates the international agreements to which the Kingdom of Saudi Arabia has acceded. What are Saudi Arabia’s plans to join the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty?
3. Your submission identifies the results of physical copyright enforcement campaigns and online inspection campaigns last year as well as the destruction of more than 3,500,000 items seized by the Ministry of Media and more than 2,000,000 items seized by Saudi Customs in previous years.
 - a. What criminal penalties and fines or civil damages were assessed against those responsible for the manufacturing, distribution, sale, or trafficking of the seized counterfeit goods, pirated goods, or pirated digital items?
 - b. Where did the seized counterfeit goods originate? Were they manufactured or created in Saudi Arabia, or were they imported into Saudi Arabia?
4. Your submission states that Saudi Arabia’s “patent linkage system” mentioned in the 2021 Special 301 submissions by industry refers to Circular Number 7448 issued by SFDA “that does not count as regulations that must be adhered to.” Is your submission therefore saying that Saudi Arabia does not have an effective mechanism for the early resolution of potential pharmaceutical patent disputes?

Government of Taiwan

1. In your submission, you mentioned proposed Copyright Act amendments that will “turn digital infringement practices into offences indictable without a complaint,” and noted that “[e]fforts to get the amendment enacted are underway.” At what stage of the legislative process are the amendments?
2. Your submission discussed the difficulty of users and collective management organizations (CMOs) agreeing on royalty rates, as well as describing a feeling of mistrust between the two sides. What actions are being taken by TIPO or others to work towards building a relationship between users and CMOs?

Government of Thailand

1. The 2021 Special 301 submission by the International AntiCounterfeiting Coalition (IACC) states that brands continue to experience significant delays in obtaining trademark registrations, with some applications pending for over five years. Can you explain steps Thailand has taken or can take to address this concern?
2. Your submission states that the Department of Intellectual Property has taken into account the public comments submitted on draft amendments to the Patent Act and that the amendments will be proposed to the Cabinet for consideration. Can you explain when the amendments will be proposed to the Cabinet?
3. Your submission states that Thailand is amending its Copyright Act in two phases, and that the Thai House of Representatives approved the first phase of the amendment, which covers, among other things, provisions that would allow Thailand to accede to the WIPO Copyright Treaty. Your submission also states that the House of Representatives set up an ad-hoc committee to consider the bill on January 27, 2021.
 - a. Can you explain when the bill will be considered by the Parliament?
 - b. Regarding the second phase of the amendment of the Copyright Act, which will include provisions that would allow Thailand to accede to the WIPO Performances and Phonograms Treaty, your submission states that the Department of Intellectual Property is developing a draft amendment. Can you explain when the draft will be made available for public comment, and when Parliament will consider it?

Government of the United Arab Emirates

1. Your submission states that the “UAE is currently in the final stages of establishing a publishing collecting society in the UAE.” What are the UAE’s plans to establish collecting societies for other types of copyrighted works, such as sound recordings?
2. The 2021 Special 301 submission by the International Anti-Counterfeiting Coalition asserts that non-deterrent penalties in the UAE for intellectual property violations has frustrated right holders and allowed recidivism, and that that provisions in the 2016 Intellectual Property Law for significantly increased penalties have yet to materialize.
 - a. What criminal penalties and fines were assessed against those involved in manufacturing, selling, selling, or trafficking in counterfeiting this past year?
 - b. Does the UAE intend to increase the assessed penalties and fines for criminal trademark infringement?
3. USTR has identified the Ajman China Mall as a notorious market for counterfeiting and piracy for several years, yet right holders continue to complain that the warehousing, distribution, and sales of counterfeit goods at the mall and surrounding stores and warehouses continues unabated. Does the UAE intend to address the counterfeiting activities at the Ajman China Mall, and how?

Government of Ukraine

1. Your submission summarizes Ukraine’s efforts to address shortcomings in the system for collective management organizations (CMOs), an issue that has been highlighted in previous Special 301 Reports. In particular, your submission notes that decisions on accreditation of CMOs selected in the spheres of “public broadcasting of musical non-dramatic works” and “public performance of musical non-dramatic works” are under consideration at the Ministry for Development of Economy, Trade and Agriculture. Please elaborate on the timeframe for making those decisions.
2. Your submission notes that the State Enterprise “Ukrainian Intellectual Property Institute” has started executing functions of NIPA, the new IP agency.
 - a. What is the relationship between the State Enterprise and NIPA during the transition described in your submission, and what will the relationship be after the transition?
 - b. Is the Institute part of the new IP agency, or is it a separate entity?
 - c. Has the Supervisory Board for the NIPA been appointed?
 - d. What is the timeframe for appointing the Head of the NIPA?
3. In your submission, under the heading “Legalization of unlicensed software at executive authorities,” you mentioned an “annual planned inventory of software at executive authorities” and using information collected during the inventory for “further meetings with the representatives of software producers.”
 - a. What plans do you have to meet with software producers following the completion of the annual inventory of software at executive authorities?
 - b. What methodology is used for conducting the annual inventory of software at executive agencies and how does that methodology take into account industry concerns?
 - c. Given that use of unlicensed software by Ukrainian government agencies has been raised in previous Special 301 Reports, will you share the information collected during the annual inventory of software at executive agencies with industry and/or the U.S. Government?
4. Under the current draft Law on Copyright and Related Rights, can a right holder file a claim of infringement on its own behalf or must the claim be filed through an advocate or attorney?

ACT | The App Association

1. On China, your submission expresses concern that intellectual property can be deemed “an essential facility for business operation” and that right holders may be subject to competition law enforcement for refusals to license their intellectual property. Have Chinese authorities deemed any intellectual property held by app developers to be such an essential facility?
2. Your submission states that “small app businesses depend on customer trust to grow and create more jobs, an endeavor that can only be maintained through the use of the strongest technical protection measures (TPM) available, including encryption,” but that “the Chinese government continues to threaten the ability to utilize TPMs, primarily encryption.” What are the specific ways in which the Chinese government threatens the ability to utilize TPMs?
3. Your submission states that “Indian patent law is inconsistent with the TRIPS Agreement.” Please identify these inconsistencies.
4. Your submission states that Thailand “continues to facilitate an environment where counterfeit and pirated software markets thrive because of limited legal enforcement mechanisms and a lack of rule of law.” Please elaborate on the “limited legal enforcement mechanisms and a lack of rule of law” that is facilitating an “environment where counterfeit and pirated software markets thrive” and identify steps Thailand should take to remedy this situation.
5. Your submission states that the Vietnam “continues to present challenges to App Association members with respect to IPR policies and enforcement, where inadequate frameworks and inconsistent enforcement undermine confidence.” Can ACT further explain where Vietnam’s IP framework is inadequate and how its IP enforcement undermines ACT members’ confidence?
6. Your submission points out that the Russian market has presented challenges to ACT’s members, noting that “Russia has continued to foster an environment that permit extensive software piracy.” In what ways does Russia create an environment that fosters software piracy? Are intellectual property laws inadequate? Is effective enforcement through the police, courts, and customs an issue?

Alliance for Safe Online Pharmacies

1. Please explain and provide details regarding your assertion that India has not implemented its obligations under the WIPO Internet Treaties.
2. Please elaborate on your statement that “India’s patent law is inconsistent with the TRIPS Agreement.”
3. Are there any countries that have adopted policies in response to the COVID-19 pandemic that have contributed to the supply of counterfeit pharmaceutical products? If so, please identify the countries and the policies.
4. What percentage of the illicit pharmacies in China are directed to the domestic market versus the international market? Are there differences in methods and current levels of enforcement based on the targeted audience?
5. Your submission asserts that many online “Canadian” pharmacies are operating out of countries such as India, Hong Kong, and Singapore. Please provide further information on the sources that support this statement, such as studies, reports, or other information.

Alliance for Trade Enforcement

1. Your submission states that the amendments to the Korea Copyright Act are troubling, highlighting the expansion of the right of digital audio transmission. Can the AFTE expand on how this right has “caused legal and commercial uncertainty” and which entities would be harmed or benefit?
2. On Brazil, your submission alleges that “the majority of those arrested on suspicion of criminal IP infringement never face criminal charges or prosecution.” What factors might explain the lack of criminal charges or prosecution?
3. You referenced India’s “unique disclosure requirements for inventions using biological materials.” Please elaborate on those “unique disclosure requirements.”

American Chamber of Commerce in Argentina

1. Article 83 of Law No. 24,481 on Patents and Utility Models provides for the grant of preliminary injunctions in patent infringement cases in Argentina. Your submission notes that your member companies have suffered patent infringements from local companies and that the process of obtaining injunctive relief has become “very lengthy” and “burdensome,” thereby denying them relief. Could you elaborate as to what is meant by “burdensome” and “very lengthy”? What has been the impact on patent holders (or their licensees)?
2. Your submission notes that the north Argentinian border is the main path for counterfeit products. Do counterfeit goods primarily come from outside Argentina? If so, does the Chamber have a clear idea of the exact sources?
3. Your submission claims that Argentina has “remarkable deficiencies” with respect to copyright protection, with very weak levels of enforcement against piracy. Do you have specific examples of copyright piracy that AmCham Argentina members have experienced?

American Apparel & Footwear Association

1. Your submission indicates that China's measures for bad faith trademarks have not been effective in addressing the problem and that "members continue to face an unacceptably high number of bad faith trademarks in China." Would you recommend that China adopt additional measures, or is the problem with implementing and enforcing existing measures? If additional measures are needed, please elaborate on specific proposals to address bad faith trademarks.
2. Regarding China, please provide further details with respect to your statement that "[i]nfringers are also quickly adapting their activity to straddle e-commerce marketplaces and social media platforms, which may not squarely fall within the current scope of the E-Commerce Law's intellectual property rights protection system."
3. Your submission notes that Guatemalan Customs officials cooperate on counterfeit seizures, but you nonetheless recommend that USTR place Guatemala on the Priority Watch List as "one of the key countries tied to the production of counterfeit garments," among other concerns. Last year, AAFA did not recommend that USTR list Guatemala in the Special 301 Report. Please explain how the situation has changed since the 2020 Special 301 review and why you are recommending a Priority Watch List designation this year?
4. Although your "members report that they have seen little, if any, improvement on intellectual property practices," you recommend that "Pakistan should move from the Watch List to the Priority Watch List."
 - a. Would you please explain this reasoning in more detail?
 - b. Over the last several years, Pakistan has provided public awareness campaigns for IP protection and enforcement, increased coordination in enforcement matters between government agencies, and established IP tribunals. Have AAFA members seen any improvements as a result of these developments?
5. Your submission recommends that USTR place certain countries that produce counterfeit goods on the 2021 Priority Watch List, including Bangladesh, Cambodia, China, Guatemala, Indonesia, Pakistan, Philippines, Thailand, and Turkey. Which of these countries are most responsible for the losses your members have faced from losing market share to counterfeit products? In addition, your submission notes that many apparel companies cancelled orders or cut back production in Bangladesh during the COVID-19 pandemic, resulting in cheap available labor and an explosion of counterfeit production in Bangladesh. According to your submission, AAFA members report that many counterfeiters are now looking at Bangladesh – as opposed to China – to have fake goods made even quicker and cheaper. Are you able to calculate the losses your members have faced, by percentage or dollar value, as a result of the increase in counterfeit production in Bangladesh?
6. Regarding Italy, your submission cites the lack of a comprehensive examination of trademark applications, in combination with an inconsistent approach to enforcement cooperation, as the primary reasons for placement on the Watch List. Many other countries not on the Watch List can be categorized as having these same issues. Could AAFA elaborate as to what warrants its recommendation for placing Italy on the Watch List in this instance?

American University Washington College of Law, Program on Information Justice and Intellectual Property

1. In your submission, you seem to indicate that expanding exceptions and limitations in copyright is in the public interest. How should the United States consider the interests of right holders, especially artists, musicians, and writers, in attempting to achieve balance in copyright?

Asia Video Industry Association

1. Regarding China's recent amendments to the Copyright Law, your submission claims that "there remains a lack of clarity . . . over whether a live sports broadcast would satisfy the originality criteria needed for protection under the Draft Amendments" and that "it is disappointing that such broadcasts are not explicitly included as audio-visual works under the Draft Amendments." In your view, would a regulatory clarification or a judicial interpretation be able to address the proper standard of originality for live broadcasts? Please explain why or why not.

Association for Accessible Medicines

1. Your submission requests USTR to “pursue trade policies that will facilitate the growth of the U.S. generic and biosimilar drug industry.” Do you have recommendations for how the 2021 Special 301 Report can best of balance the interests of both the generic/biosimilar industry and innovative pharmaceutical industry to achieve the greatest benefit for the U.S. economy?
2. You state that, “for essential drugs to be imported, the Russian price registration system has a minimum price threshold requirement” that “prevents U.S. and other generic pharmaceutical companies from obtaining a reasonable retail price.” What percentage of drugs sold in Russia are on the Essential Drug List??
3. Your submission states that “[f]or essential drugs to be imported, the Russian price registration system has a minimum price threshold requirement (out of 12 reference countries).” Please explain why, as you asserted, this “prevents U.S. and other generic pharmaceutical companies from obtaining a reasonable retail price.”
4. On India, your submission states that “[r]ecently Central and State drug control authorities have started to collaborate more effectively, providing a license to manufacture the drug product only after satisfactory outcome of a joint inspection conducted by both state and central drug control officers.” Was this improvement in collaboration prompted by a legislative or regulatory change, or some other event?
5. How should USTR take the COVID-19 pandemic into account when drafting the 2021 Special 301 Report? Please explain your reasoning.

Audiovisual Anti-Piracy Alliance

1. Your submission claims that “copyright infringement has increased to unprecedented levels in Saudi Arabia.” Please provide the reports, studies, or other data you are relying on to support this claim.
2. Your submission cites to the 2019 Special 301 submission from beIN Media Group, LLC and Miramax, LLC for the statement that “IPTV apps downloaded onto beoutQ boxes continue to offer [pirated content].” The 2019 Special 301 submission identified 6 non-beoutQ pirate IPTV apps that users could download to the beoutQ set-top boxes from the beoutQ custom app store.
 - a. Please provide background on the state of the beoutQ set-top boxes when beoutQ went offline. For example, did the beoutQ set-top boxes stop working altogether until a new operating system and new pirate IPTV apps were installed, or did the pirate IPTV apps that were downloaded to the beoutQ set-top boxes continue working uninterrupted? Is there evidence that a significant number of people took steps to enable and use the non-beoutQ pirate IPTV apps on the beoutQ set-top boxes?
 - b. Have there been any developments with the beoutQ set-top boxes since beoutQ went offline or is the state of the beoutQ set-top boxes in Saudi Arabia the same as it was in August 2019?
3. Your submission notes that despite the recent Egyptian legislation criminalizing piracy online, the lack of effective protection and enforcement of intellectual property rights encourages piracy. Can AAPA expand upon any defects in the recent legislation that leads to such expansion of piracy?
4. Your submission claims that “a number of Saudi-based pirates continue to take advantage of the deficient copyright law” in Saudi Arabia. Can AAPA expand on your views regarding how the law is deficient?

beIN Media Group, LLC and Miramax, LLC

1. Your submission claims that Chinese authorities have stated that they do not impose any restrictions on design, manufacture or sale of illicit streaming devices (ISD) boxes for export. Have enforcement actions been requested against ISD manufacturers that were refused by the Chinese authorities?

Biotechnology Innovation Organization

1. In what ways, if any, should USTR take the COVID-19 pandemic into account when drafting the 2021 Special 301 Report? Please explain your reasoning.
2. Your submission states that “Article 59 of China’s Biosecurity Law enacted in October 2020 requires that foreign biotech firms when accessing data related to human genetic resources in China must partner with local Chinese entities in the R&D process and that the Chinese partnering entity must participate substantively in the entire course of research and share in any relevant interests.” In practice, what has fallen within the scope of “data related to human genetic resources of China?”
3. Your submission states that Saudi Arabia does not provide effective protection for regulatory data, claiming that the Saudi Food and Drug Authority (SFDA) grants marketing authorization for unauthorized generic companies, apparently relying on test data submitted by the innovator. Saudi Arabia’s 2021 Special 301 submission claims that “the information was acquired independently without relying on any information provided in the innovative product’s file.” Please provide the basis for your statement that SFDA apparently relied on test data submitted by the innovator in granting marketing authorization for unauthorized generic companies.
4. How have the changes to Mexico’s procurement practices have been operating in practice? Have any specific patented medicines been directly affected so far?
5. Has Korea fulfilled its commitment to provide “additional written information” within 30 days after conclusion drug price negotiations with NHIS, regardless of whether the negotiation ended in agreement? If so, can you provide feedback on the quality of the written information provided?
6. Your submission notes concerns with the 2019 EU legislation regarding Supplementary Protection Certificates (SPC) and claims that the adopted exemption to SPC rights frustrates the fundamental purpose of these rights, specifically that recent studies indicate significant losses in revenue, R&D expenditure, and jobs for the European biopharmaceutical industry as a result. Could you please elaborate on the nature of the significant losses in revenue, R&D expenditure, and jobs and provide examples?

Brazil National Confederation of Industry and American Chamber of Commerce for Brazil

1. Your submission notes that Brazil's National Intellectual Property Strategy (ENPI) was launched at the end of 2020, establishing action plans with quantifiable targets for its main objectives. Are the action plans publicly available? If so, can you provide copies? Are there any aspects of ENPI that address copyright?
2. Your submission identifies the reduced patent backlog between August 1, 2019, and January 20, 2020. Have there been further reductions in the patent backlog since then?
3. Your submission notes increased efforts by the Brazilian government to take action against websites that stream illegal content. Have any criminal investigations or actions been taken against the owners or operators of the websites?

BSA | The Software Alliance

1. Your submission notes that “[t]he use of unlicensed software by governments is particularly challenging to BSA members” and urges the U.S. Government to use mechanisms such as Special 301 to engage with trading partners on the issue.
 - a. Please provide a list and summary of the countries (and/or those countries’ government ministries) that have measures (laws, regulations, etc.) that require government entities to acquire and maintain authorized software licenses.
 - b. Please elaborate further on specific countries whose governments are using unlicensed software?
2. Please identify the specific proposed or implemented policies of China, such as the “sector-specific outsourcing or IT risk management frameworks” described in your submission, that require source code review and raise concerns about the protection of trade secrets. Also, what specific sectors have been impacted by the source code requirements in China?
3. Please elaborate on how India’s trade secret regime undermines your members’ ability to protect commercially valuable, secret information.

China Chamber of International Commerce

1. Your submission notes that the Beijing High People's Court "corrected the previous misconceptions regarding adjudication of sports programs" in two recent cases.
 - a. Given China's civil law system in which court decisions do not have binding authority on other courts, do the recent rulings from the Beijing High People's Court fully address the concerns regarding the lack of copyright protection of live sports broadcasts?
 - b. Should China instead amend its copyright regulations to clarify the circumstances in which live sports broadcasts should be considered protected audio-visual works?
2. What efforts are the Chinese government making to prevent the sale and distribution of counterfeit goods through e-commerce platforms?
3. How can China's judicial system be improved with respect to intellectual property enforcement to ensure timeliness, fair judgment, and compliance with verdicts?

CIOPORA

1. In your submission on India you advocate for an exclusion of ornamental and fruit varieties from compulsory licensing of plant breeders' rights based on public interest. Please explain your statement that "there is in principle no ... public interest in the commercialization of vegetatively reproduced fruit and ornamental varieties."
2. Your submission indicates that your members have experienced challenges when enforcing their plant breeder's rights in China and referenced "loopholes in [China's] enforcement system." Can you please provide more specific information and examples of what challenges or loopholes exist in the Chinese enforcement system, and what, if any, engagement have you had with Chinese officials on these issues?
3. In your submission, you indicate that the Community Plant Variety Office (CPVO) of the European Union and several other plant breeders' rights offices in the world are willing to share with the Chinese government the test reports for varieties that have already been examined in their countries.
 - a. What is the status of that cooperation?
 - b. With this cooperation, will China be in the position to provide protection for all genera and species that have received protection in those countries?
4. Your submission states that "[o]nly a limited number of species is protectable in China. For the breeders of other species, which are not on the list of protectable species, no protection is provided for." Approximately what percentage of species are protectable in China?
5. Your submission states that "[t]he Chinese Seed Law therefore adds 'promotion' as a novelty defeating act, which is broader than sales. The Seed Law also added two more additional novelty defeating circumstances. . . . These additional circumstances are particularly concerning for plant breeders because there is no requirement that these acts be performed by the breeder or with the breeder's permission." How many plant varieties have lost novelty under the "or promoted" provision or the two additional identified novelty defeating acts?

The Clear Sky Initiative

1. Your submission states: “Despite the positive fact that the amended Art. 176 of the Criminal Code of Ukraine establishes that financing of operations related to copyright and related rights infringement is classified as a crime since 2017, due to the vagueness of definitions, advertising intermediaries and advertisers cannot be effectively made criminally liable. So far, the courts of Ukraine have not passed any sentences for online piracy financing.” Your comment also states that “the first criminal prosecution in Ukraine was opened for financing of piracy operations.”
 - a. Have any additional criminal prosecutions, or sentences, taken place since 2020 for the financing of piracy operations?
 - b. Does the Cyber Police Department continue to conduct large-scale searches of representatives of the advertising industry suspected of financing piracy sites through advertising, as your submission reported occurring in 2020?

Computer & Communications Industry Association

1. Regarding the European Union's Copyright Directive, your submission "identifies Articles 15 and 17 as concerns and as they represent a departure from global IP norms and international commitments, and will have significant consequences for online services and users. These rules diverge sharply from U.S. law, and will place unreasonable and technically impractical obligations on a wide range of service providers, resulting in a loss of market access by U.S. firms."
 - a. In stating that these articles "represent a departure from global IP norms and international commitments," are you asserting that the Copyright Directive violates international treaties? If so, would you please explain what international commitments the Copyright Directive violates?
 - b. Although the Copyright Directive provides the framework, Member States must transpose these requirements into their national laws. Are you concerned that Member States will not be able to transpose the Copyright Directive in a manner that does not depart from international norms and commitments?
2. Your submission states that "China has sought to block these U.S. cloud service exporters through discriminatory practices that force the transfer of intellectual property and critical know-how, reputable brand names, and operation over to Chinese authorities and companies in order to operate in the market." Has there been any improvement with respect to the forced transfer of intellectual property and critical know-how, reputable brand names, and operation in the past year?

Confederation of Indian Industry

1. U.S. industry stakeholders raise concerns about the implementation of Paragraph 32 of the 2013 Drug Price Control Order (DPCO).
 - a. How has the implementation of that Order impacted your constituents?
 - b. Do you have any responses to 2021 Special 301 submission by the Pharmaceutical Research and Manufacturers of America that “the potential benefit of the provision” exempting patented products and orphan drugs “has not been realized due to a significant delay in implementation, and applications made by industry remain pending?”
 - c. Do you have any responses to the 2021 Special 301 submission by the US-India Strategic Partnership Forum about “an evolving pricing regime that is discriminatory, unpredictable and opaque,” with “potential for inclusion of patented medicines in the [National List of Essential Medicines] and thereby a threat of direct price setting under the DPCO”?
2. According to your submission, States in India have developed well-established systems for checking domestic and cross-border copyright infringements. Have the states converged on a specific approach for checking domestic and cross-border copyright infringements, or do they each have separate systems?

Consortium for Common Food Names

1. Your submission notes that, as part of the ongoing EU-Australia FTA negotiation process, Australia published a list of EU GIs for opposition, and CCFN “welcome[d] the transparency to date of the Australian government in soliciting public comment on draft FTA text related to this topic.” Yet, CCFN also states that Australia is “not committed to following an objective, evidence-driven process.” Please explain your views on how Australia’s process is not an objective, evidence-driven process and specifically identify any difficulties your members faced during the opposition process.
2. Your submission notes that in 2016, Indonesia issued text proposing changes to its GI regulations, and that the proposed changes are “deeply flawed.” Can CCFN further explain how Indonesia’s proposed changes to its GI regulations are deeply flawed and how your concerns would be best addressed?
3. Your submission states that Costa Rica “has not issued confirmations regarding the scope of protection of previously registered GIs nor provided assurances to the U.S. that its FTA market access rights will not be further eroded in the future by subsequent GI applications.” Costa Rica issued Executive Decree No. 41572-J-COMEX, which, among other things, appears to delineate grounds for refusing to provide GI protection and provide procedural steps for opposing GI applications. Costa Rica’s 2021 Special 301 submission notes that, in 2020, no national registration requests were filed and the 6 applications filed under the Lisbon Agreement followed the process provided for in Executive Decree No. 41572-J-COMEX. Does Executive Decree No. 41572-J-COMEX resolve CCFN’s concerns? If not, what concerns remain?

Emirates Intellectual Property Association

1. Your submission states that multiple Federal entities and multiple entities in each Emirate have existing enforcement procedures depending on where the infringement takes place. Right holders have told USTR that they are unable to find the IP enforcement procedures for many of these entities. Please identify the location where the IP enforcement procedures are published for each Federal and Emirate-level entity with IP enforcement authority.
2. Your submission states that the multiple Federal and Emirate-level entities with IP enforcement authority “work closely together to ensure enforcement.” Please identify the procedures for how these multiple entities coordinate on investigating and enforcing IP violations that occur across multiple jurisdictions.
3. As the 2021 Special 301 submission of the International Intellectual Property Alliance points out, UAE passed federal legislation 18 years ago that provides for the possibility of collective management organizations (CMOs). What steps are needed before the government will permit rights holders to establish a CMO for each of the copyright industries (publishing, music, etc.) and commence collective licensing activities, and when do you expect these steps to occur?

Engine Advocacy

1. According to your submission, Article 17 of the European Union’s 2019 Copyright Directive “will open smaller and startup Internet platforms to substantial new costs and risks.” To what extent does your submission account for potential variation in how individual member states implement Articles 15 and 17?
2. Your submission provides that “the specific approach China has proposed for allowing dual administrative and judicial adjudication is unclear. There are no articulated standards for when a dispute could or would be taken to the administrative agency versus the court. Dividing enforcement authority in this way will increase uncertainty for startups and open doors to abuse.” What interaction have you seen thus far between administrative and civil enforcement of patents?
3. Your submission claims that “[r]ecent changes in China will also over-amplify the damages and relief available in patent cases, creating a fertile foundation for abuse.” Have you seen a rise of abusive litigation in China as a result of the increased availability of damages?

The Football Association Premier League Limited

1. Regarding China, your submission claims that there is “unnecessary uncertainty, at least amongst certain judges and academics, over whether a live sports broadcast would satisfy the originality criteria required to qualify for protection under the Copyright law.”
 - a. Has the Premier League been associated or involved in any litigation in China involving this legal issue, and if so, with what result?
 - b. Which cases in Chinese courts do you find the most influential in support of your view on the originality of live sports broadcasts?
 - c. What are your views on the amendments to the Copyright Law that will enter into force in June?
2. Your submission states that “attempts to pursue enforcement action against Chinese-based pirates have been met with frustration, particularly where they have successfully obfuscated their identity, deliberately restricted the content they offer to non-Chinese channels and/or where they are careful not to carry out sales within mainland China itself.” Do the restrictions of content offerings and location of sales result in Chinese authorities not having jurisdiction, or is it a question of priorities for enforcement efforts?

Footwear Distributors & Retailers of America

1. Your submission states: “Footwear companies spend hundreds of millions of dollars each year to design, produce, and ship innovative footwear to Americans. Counterfeit footwear threatens jobs in our industry and puts our consumers’ trust at risk.” Can you provide the estimated loss in dollar value to American workers and American businesses in the footwear industry due to the proliferation of counterfeit goods?
2. Your submission states that China is the number one source of counterfeit and pirated goods imported into the United States, with best-selling knock-off footwear from best-selling American brands. Your submission identifies the provinces of Guangdong, Zhejiang, and Fujian as posing particular challenges for footwear brands, because all three are major footwear hubs, producing both legitimate footwear as well as counterfeit products. With respect to the production of counterfeit products, can you provide, either by percentage or dollar value, of the losses your members have faced from counterfeit footwear coming from these three provinces and from China as a whole?
3. Please elaborate on the request in your submission for India to “elevate protection for famous marks.” How, in particular, would you suggest India elevate this protection?
4. Your submission states that, while Indonesia will continue to become increasingly important as key emerging markets of footwear consumers, FDRA is concerned about the “substantial lack of IP protection” in Indonesia and that “much more has to be done to strengthen IP protection and enforcement” in Indonesia. Can you further explain you and your members’ intellectual property concerns in Indonesia and how the Indonesian government could improve its intellectual property protection and enforcement?
5. In 2019, the Russian government issued Resolution No. 860 “On the approval of rules for the mandatory labeling of shoes” establishing a mandatory labeling regime for footwear. In 2020, Resolution No. 216 amended Resolution No. 860 to extend the implementation deadline until mid-2020. One of the labeling regime’s goals is to combat counterfeit goods in the Russian market by issuing unique tracking identifiers utilizing QR codes, RFID chips, and other technologies.
 - a. Does this mandatory labeling regime address some of the concerns expressed in your submission about the high level of counterfeit goods in Russia?
 - b. Do you have concerns about the breadth of product-specific data that must be provided in order to obtain the labels?

Fraunhofer USA

1. Please elaborate on the statement in your submission: “What is considered to be a FRAND negotiation ... appears to be approached very differently in India compared to the US.” What are the implications and consequences of India’s approach for your organization?
2. Your submission expresses concern about certain decisions of Chinese courts in relation to FRAND licensing disputes and the use of anti-suit injunctions.
 - a. To what extent would revisions to the IP policies of standards development organizations help address these concerns?
 - b. Do you recommend other initiatives?
 - c. Should governments play a leading or complementary role in addressing these concerns?
3. What standards do you recommend be applied with respect to FRAND negotiations and why? In what way does China diverge from these standards?

Indian Pharmaceutical Alliance

1. How has the COVID-19 pandemic impacted the availability of counterfeit medical products in the Indian market?
2. Your submission notes that 426 pre-grant oppositions were received in India in FY2018-2019, and 399 were disposed of. Does that mean that the time to review those 399 oppositions took less than a year, or were some of those 399 oppositions holdovers from previous years?

Intellectual Property Owners Association

1. Please explain whether, and to what extent, the concerns expressed in your submission regarding India's National Manufacturing Policy (2011) and National Competition Policy (2011) were abated by India's National Intellectual Property Rights Policy (2016).
2. Your submission states that India's patent working requirement "appears to include situations when patent holders import the related technology into the country, but do not locally manufacture it." Please explain how India's patent working requirement appears to include these situations and, if these situations occurred, provide information about these situations.
3. Your submission lists "high burdens of proof" as one of various obstacles to effective civil enforcement against trade secret misappropriation in China. Have provisions of the amended Anti-Unfair Competition Law on burden shifting been helpful to date in that regard?
4. Your submission notes that, in July 2020, Indonesia issued Presidential Regulation No. 77/2020 on government use of compulsory licenses "without consulting stakeholders and the final form contains various concerning provisions." Please elaborate on the "various concerning provisions" in Presidential Regulation No. 77/2020.
5. You stated that "given India's appointment as an International Search Authority for the Patent Cooperation Treaty (PCT), it is possible that the requirement to furnish examination results for co-pending applications conflicts with PCT rules." Please explain how the requirement to furnish examination results for co-pending applications potentially conflicts with PCT rules and, if conflicts have occurred, provide information about the conflicts.
6. Your submission provides that "anti-suit injunctions have arguably tipped the scales in favor of state-owned businesses" in China. Have anti-suit injunction proceedings in that involve state-owned businesses been different from proceedings that do not involve state-owned businesses?

International AntiCounterfeiting Coalition

1. On China, your submission indicates that attempts to pursue trade secret-related enforcement under the amended Anti-Unfair Competition Law (AUCL) have been frustrated by some courts' narrow reading of the law. Please identify which elements of the AUCL have most often presented obstacles.
2. On Kuwait, your submission states that the comments received from your members regarding intellectual property enforcement remain largely unchanged from last year; that Kuwait's anti-counterfeiting enforcement regime is described as "virtually nonexistent." This past year, the U.S. Government received reports that (1) Kuwait Customs is seizing significantly more counterfeit goods coming through its new Port of Doha than Customs has seized in the past; (2) the Kuwait Copyright Office now has inspection teams with the authority to submit cases directly to the courts; and (3) the Trademark Office now has the authority to conduct inspections. To support your statement that Kuwait's anti-counterfeiting regime remained virtually nonexistent, please enumerate and describe the interactions your members have had with these or other Kuwaiti Authorities this past year when attempting to enforce their intellectual property rights.
3. Your submission says that right holders' feedback with regard to their concerns relating to IP enforcement in UAE this year "remained largely unchanged from that heard in previous years." UAE's 2021 Special 301 submission on pages 3-4 describes what it claims is "substantial progress in improving its domestic counterfeit enforcement."
 - a. In view of these claimed improvements, please explain why right holders' feedback remained largely unchanged from that heard in previous years.
 - b. Please list other improvements that right holders would need to see in order to change their feedback for the better next year.
4. Your submission notes that IACC members greatest criticisms of the Indian regime involved delays in the court system and trademark office. Have IACC members experienced any improvement in the pace of court cases since the passage of the Commercial Courts Act in 2015?
5. Your submission states that despite increased seizures during the past year, the Philippines' border control measures are insufficient. Can IACC further explain the steps the Philippines should take to address is concern?
6. Your submission states that Turkey has developed an adequate IP regime but that it should be placed on the Priority Watch List primarily because the IP regime is undermined by a lack of expertise, most notably within the judiciary and among prosecutors. Please provide some specifics in relation to the seriousness of the problems with judiciary system in Turkey and point out those elements that contribute most heavily to the recommendation for placement on the PWL.

International Intellectual Property Alliance

1. On Brazil, your submission notes that there is a need to “ensure that law enforcement agents all over the country . . . have access to the necessary legal tools to launch effective criminal prosecutions against major online piracy operators.” Can you elaborate more on that point? Would Brazil need to pass certain types of laws for law enforcement to have access to these legal tools?
2. You recommended that USTR list Pakistan as a Watch List country last year, but you did not recommend that Pakistan be listed this year. Were there any material changes in IP enforcement or protection or market access for U.S. creators this past year?
3. Your submission states that Vietnam’s Authority of Broadcasting and Electronic Information (ABEI), under the Ministry of Information and Communication (MIC) and the police unit A05, have begun enforcing a decree to take action against dozens of infringing websites in Vietnam, and that Vietnam’s latest draft amendments to the IP Code include measures to implement the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT). Yet, IIPA recommends that USTR move Vietnam from the Watch List to the Priority Watch List. Please further explain the reasons for your recommendation that Vietnam be elevated to the Priority Watch List.
4. Your submission notes that Argentina is ranked third highest for music piracy in the world, after China and India. With such a serious situation in Argentina does IIPA have specific recommendations to address this, such as legislative or enforcement initiatives?
5. Can you explain how proposed legislation (Bill No. 4537) in Ukraine changes the composition of the CMO accreditation board (as proposed in earlier drafts of the bill)? What would be the effects?
6. On Switzerland, your submission states that the revisions to Article 77i have placed right holders in a worse position than they were following the *Logistep* decision. While the Copyright Act allows right holders to use personal information (including IP addresses) for filing criminal complaints it does not allow for the collection or processing of this information solely to bring civil claims. Has anyone tested the new law in terms of using IP addresses in a civil or criminal complaint? If so, were any of the complaints dismissed and, if so, why?

International Olympic Committee

1. To describe the difficulties that sports right holders have experienced in protecting their intellectual property in Saudi Arabia, your 2021 Special 301 submission references your 2020 Special 301 submission, which discusses challenges bringing lawsuits against beoutQ and its facilitators. Have sports right holders experienced difficulties in enforcing their intellectual property rights in Saudi Arabia after beoutQ went offline, or against entities other than beoutQ and its facilitators?
2. Please provide further details regarding the “ongoing, significant challenges in Saudi Arabia with respect to IP protection and enforcement.”

Internet Association

1. With respect to the specific draft notices of China's Ministry of Industry and Information Technology identified in your submission, please identify the specific provisions that raise concerns about the transfer of intellectual property.
2. According to your submission, the text and data mining (TDM) exceptions in the European Union's 2019 Copyright Directive limit "who can legally engage in machine learning." Please explain your views on how the TDM exceptions do this, and include any reports related to implementation in EU member states.
3. Regarding India, your submission argues that "the lack of a clear safe harbor framework for online intermediaries in the Copyright Act means that internet services are not necessarily protected from liability in India for user actions in case of copyright infringements." Are you aware of any online service providers choosing not to operate in India out of fear of uncertain liability?
4. How does the Russian "Mirrors Law" create market access barriers to U.S. Internet service providers? Does the law not apply to domestic service providers?

Knowledge Ecology International

1. Are there any national policies that foreign countries have adopted in response to the COVID-19 pandemic that you recommend that we highlight in the 2021 Special 301 Report and why? How would those examples fit with the purpose of the Special 301 review?
2. According to your submission, Special 301 submissions are primarily from right holders and their representatives. Which types of organizations or individuals would you suggest should also submit comments that did not submit comments this year, and how would you recommend encouraging their involvement?
3. In KEI's view, are there foreign countries that lack adequate and effective protection and enforcement of intellectual property rights? What foreign countries should USTR identify in the 2020 Special 301 Report?

La Liga Nacional de Fútbol Profesional

1. Your submission expresses a concern “that there may have been a cultural shift in Saudi Arabia such that piracy is now generally accepted as an appropriate and, indeed, natural means of watching sports and other media content.” Do you have studies, reports, or other data showing a sustained increase in the consumption of pirated content in Saudi Arabia, or showing that the consumption of pirated content in Saudi Arabia is significantly worse than other countries in the MENA region?
2. Your submission states that “beIN and rights holders remain unable to seek civil remedies against piracy” in Saudi Arabia
 - a. Has LaLiga or any of its associated sports companies and clubs sought civil remedies in Saudi Arabia against organizations or individuals involved in piracy operations in 2020 or 2021? What have the obstacles or challenges that you have faced?
 - b. Is LaLiga aware of any other rights holders that sought civil remedies in Saudi Arabia against organizations or individuals involved in piracy operations in 2020 or 2021?
3. Your submission notes that despite the recent Egyptian legislation criminalizing piracy online, the lack of effective protection and enforcement of IP rights encourages piracy. Are there any deficiencies in the recent legislation that has led to such expansion of piracy?
4. According to your submission, “a number of Saudi-based pirates continue to take advantage of the deficient copyright law” in Saudi Arabia. In your view, how the law is deficient?
5. Your submission states that “piracy continues to be the primary way for Saudi citizens to watch most of their sports.” Please provide the relevant data to substantiate this assertion.

MFJ International, LLC

1. Are there any national policies that foreign countries have adopted in response to the COVID-19 pandemic that you recommend that we highlight in the 2021 Special 301 Report and why? How would those examples fit with the purpose of the Special 301 review?

National Association of Manufacturers

1. In what ways, if any, should USTR take the COVID-19 pandemic into account when drafting the 2021 Special 301 Report? Please explain your reasoning.
2. Your submission states that Saudi Arabia suffers from high levels of domestic counterfeiting.
 - a. Please elaborate on this statement, explain what “high levels” is in relation to, and provide recent studies, reports, or other data to support this statement.
 - b. What types of counterfeit goods is your submission referring to, and in what region are the goods being manufactured or sold?
3. On Indonesia, your submission states that Presidential Regulation 77/2020, which “detailed the government’s right to issue a compulsory license broadly for patents related to national defense, security or the vague circumstance of ‘very urgent need in the public interest,’” raises “significant concerns for manufacturers in a wide range of sectors.” Please elaborate on your concerns regarding Presidential Regulation 77/2020.
4. Your submission states that Australia “maintains a unique policy enabling the Department of Health to seek damages from patent holders that litigate granted patent claims and are granted preliminary injunctive relief but ultimately are unsuccessful in their litigation” and that this policy “has created a significant hurdle for companies seeking to enforce or defend their legitimate patent rights.” In October 2020, the Australian Government announced planned reforms to the notification procedures for prescription medicines that are under evaluation. According to Australia, these reforms are intended to enhance transparency and to reduce the need for protracted and costly litigation.
 - a. Would these reforms address the concerns identified in your submission?
 - b. Please elaborate on your claim that this policy is “inconsistent with Australia’s WTO commitments” under the TRIPS Agreement.

National Milk Producers Federation and U.S. Dairy Export Council

1. In which countries are you facing the most significant barriers related to the use of common names?
Please include a summary of the barriers for each of those countries.
2. What are examples of specific measures that governments have undertaken that you believe are best practices with respect to the protection of geographical indications and safeguarding the use of common names?

Pharmaceutical Research and Manufacturers of America

1. In what ways, if any, should USTR take the COVID-19 pandemic into account when drafting the 2021 Special 301 Report? Please explain your reasoning.
2. Your submission requests that USTR designate Canada, Japan, and the Republic of Korea as Priority Foreign Countries.
 - a. Can you explain how the acts, policies, and practices of these countries are more problematic for your members than countries you request be placed on the Priority Watch List, such as China, India, and Russia?
 - b. Your submission recommends that USTR designate Japan as a Priority Foreign Country in part because Japan considers factors like local clinical trials and the number of products launched in Japan when determining eligibility for pricing and reimbursement premiums. How do Japan's policies compare internationally in terms of incentives for local manufacturing, which your submission notes are used in many countries?
3. As stated in the 2020 Special 301 Report, an Out-of-Cycle Review (OCR) is a tool that USTR uses to encourage progress on IP issues of concern. OCRs provide an opportunity to address and remedy such issues through heightened engagement and cooperation with trading partners and other stakeholders. Your submission recommends that USTR conducts Out-of-Cycle reviews for Chile, Colombia, Indonesia, Malaysia, Russia, Saudi Arabia, and UAE in 2021. For each proposed OCR you recommend, please elaborate on the specific IP issue or issues of concern that you would recommend be part of the OCR, the criteria you would recommend for a successful completion of each issue, and an expected timeframe for the completion of each issue.
4. Your submission notes that "Egypt lacks effective patent enforcement, enabling manufacturers to obtain marketing licenses for follow-on products prior to the expiration of the patent on the original product. Recently, the Egyptian Government has taken steps to set up a ministerial committee with broad discretion to issue compulsory licenses." Are there instances when U.S. pharmaceutical companies have had follow-on products obtain marketing licenses prior to the expiration of its patent on the original product or when the government has issued a compulsory license?
5. Other 2021 Special 301 submissions, such as the one by the Confederation of Indian Industry, identify several improvements that have been made to India's IP regime over the past year. Do you agree with these submissions regarding the identified improvements?
6. Saudi Arabia's 2021 Special 301 submission claims that the Saudi Food and Drug Authority (SFDA) does not use or rely, directly or indirectly, on clinical studies provided with the innovative product when registering a generic product. Instead, it says that "the information was acquired independently without relying on any information provided in the innovative product's file." Please explain exactly how SFDA's registration of certain generic products is, according to your submission, contrary to Saudi Arabia's data protection rules and WTO commitments.

Public Citizen

1. Are there any national policies that foreign countries have adopted in response to the COVID-19 pandemic that you recommend that we highlight in the 2021 Special 301 Report and why? How would those examples fit with the purpose of the Special 301 review?

The Sports Coalition

1. Your submission identifies several countries (Bulgaria, China, the Czech Republic, Iraq, Malaysia, Netherlands, Switzerland, Russia, and the United Arab Emirates) as having a “material number of pirated game and event telecasts.”
 - a. What is a material number?
 - b. How were the pirated game and event telecasts identified and linked to these countries?
2. Your submission recommends UAE for the Priority Watch List because pirate services including Host Sailor and playerfs.com are operated, in whole or in part, within UAE.
 - a. Please explain how these pirate services, particularly in comparison with other pirate services, are harming your member companies to an extent that warrants placing UAE on the Priority Watch List.
 - b. Please provide the basis for your statement that these pirate services are operated, in whole or in part, within UAE.
 - c. Please outline your interactions with UAE authorities in dealing with these pirate services.
3. Have China’s recent copyright law amendments and court decisions addressed the problem of copyright protection for live sports broadcasts in China? If not, what concerns remain, and how should they be addressed?

Trademark Working Group

1. Your submission states that Bulgarian courts place undue reliance on court-appointed experts for the assessment of legal issues – not only for fact-related issues but also for legal conclusions, including matters that should be under the exclusive purview of the Courts. Do you have specific examples that demonstrate clearly the negative impact such a practice may have?

Union of European Football Associations

1. On Saudi Arabia, your submission references your 2020 Special 301 submission and notes that UEFA is not aware of any “material improvement or progress to report on in relation to the development of the enforcement of intellectual property rights in Saudi Arabia.” Has UEFA attempted to enforce its intellectual property rights in Saudi Arabia since your 2020 Special 301 submission? If not, please explain why not, and provide the basis for your statement regarding no improvement in this area.
2. Please describe and elaborate on the “material lack of relevant legal enforcement mechanisms in Iraq.”

U.S. Chamber of Commerce

1. In what ways, if any, should USTR take the COVID-19 pandemic into account when drafting the 2021 Special 301 Report? Please explain your reasoning.
2. Your submission states that the European Commission’s Pharmaceutical Strategy is considering including “conditionalities” on incentives that mean that “a company may only enjoy its intellectual property if its product is available in most/all EU markets.” This statement does not appear to come from the Pharmaceutical Strategy itself. Please provide further detail about the basis for that statement.
3. Has anyone asserted the “export” exception to Certificates of Supplementary Protection (CSP) in Canada?

U.S.-India Strategic Partnership Forum

1. Your submission states that provisions of India’s draft Personal Data Protection Bill “directly impact intellectual property of companies.” Please explain how the provisions directly impact the intellectual property of companies.
2. According to your submission, USISPF endorses the creation of a national copyright enforcement task force in India. How would this task force be created, and what are the obstacles to its creation?
3. Your submission claims that trial times have fallen dramatically since the enactment of the Commercial Court Act.
 - a. What tools exist for tracking case times?
 - b. Are there required time limits for ruling on pending motions?